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PHARMACIST PRESCRIPTION AUTHORITY AMENDMENTS

2018 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Todd Weiler

House Sponsor: _____

LONG TITLE

General Description:

This bill permits a pharmacist to prescribe and dispense a self-administered hormonal contraceptive.

Highlighted Provisions:

This bill:

- expands the definition of the practice of pharmacy to include prescribing and dispensing a self-administered hormonal contraceptive; and
- creates standards and procedures that a pharmacist must follow when prescribing a self-administered hormonal contraceptive.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-17b-102, as last amended by Laws of Utah 2015, Chapter 336

58-17b-501, as last amended by Laws of Utah 2017, Chapter 392

58-17b-502, as last amended by Laws of Utah 2016, Chapter 405

ENACTS:

58-17b-626, Utah Code Annotated 1953

S.B. 184

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-17b-102** is amended to read:

58-17b-102. Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

(1) "Administering" means:

(a) the direct application of a prescription drug or device, whether by injection, inhalation, ingestion, or by any other means, to the body of a human patient or research subject by another person; or

(b) the placement by a veterinarian with the owner or caretaker of an animal or group of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other means directed to the body of the animal by the owner or caretaker in accordance with written or verbal directions of the veterinarian.

(2) "Adulterated drug or device" means a drug or device considered adulterated under 21 U.S.C. Sec. 351 (2003).

(3) (a) "Analytical laboratory" means a facility in possession of prescription drugs for the purpose of analysis.

(b) "Analytical laboratory" does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis if the prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic use.

(4) "Animal euthanasia agency" means an agency performing euthanasia on animals by the use of prescription drugs.

(5) "Automated pharmacy systems" includes mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

(6) "Beyond use date" means the date determined by a pharmacist and placed on a prescription label at the time of dispensing that indicates to the patient or caregiver a time

beyond which the contents of the prescription are not recommended to be used.

(7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created in Section 58-17b-201.

(8) "Branch pharmacy" means a pharmacy or other facility in a rural or medically underserved area, used for the storage and dispensing of prescription drugs, which is dependent upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and approved by the division as the parent pharmacy.

(9) "Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

(10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a retail pharmacy to compound or dispense a drug or dispense a device to the public under a prescription order.

(11) "Class B pharmacy":

(a) means a pharmacy located in Utah:

(i) that is authorized to provide pharmaceutical care for patients in an institutional setting; and

(ii) whose primary purpose is to provide a physical environment for patients to obtain health care services; and

(b) (i) includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and

(ii) pharmaceutical administration and sterile product preparation facilities.

(12) "Class C pharmacy" means a pharmacy that engages in the manufacture, production, wholesale, or distribution of drugs or devices in Utah.

(13) "Class D pharmacy" means a nonresident pharmacy.

(14) "Class E pharmacy" means all other pharmacies.

(15) "Closed-door pharmacy" means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a specific entity, including a health maintenance organization or an infusion company, but not including a hospital pharmacy, a retailer of goods to the general public, or the office of a practitioner.

(16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical care functions authorized by the practitioner or practitioners under certain specified conditions or limitations.

(17) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients and prevention of disease of human subjects.

(18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a limited quantity drug, sterile product, or device:

(i) as the result of a practitioner's prescription order or initiative based on the practitioner, patient, or pharmacist relationship in the course of professional practice;

(ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or

(iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(b) "Compounding" does not include:

(i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist or pharmaceutical facility;

(ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner; or

(iii) the preparation of a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons.

(19) "Confidential information" has the same meaning as "protected health information" under the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

(20) "Controlled substance" means the same as that term is defined in Section 58-37-2.

(21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter 417, Sec. 3a(ff) which is incorporated by reference.

(22) "Dispense" means the interpretation, evaluation, and implementation of a prescription drug order or device or nonprescription drug or device under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient, research subject, or an animal.

(23) "Dispensing medical practitioner" means an individual who is:

(a) currently licensed as:

(i) a physician and surgeon under Chapter 67, Utah Medical Practice Act;

(ii) an osteopathic physician and surgeon under Chapter 68, Utah Osteopathic Medical Practice Act;

(iii) a physician assistant under Chapter 70a, Physician Assistant Act;

(iv) a nurse practitioner under Chapter 31b, Nurse Practice Act; or

(v) an optometrist under Chapter 16a, Utah Optometry Practice Act, if the optometrist is acting within the scope of practice for an optometrist; and

(b) licensed by the division under the Pharmacy Practice Act to engage in the practice of a dispensing medical practitioner.

(24) "Dispensing medical practitioner clinic pharmacy" means a closed-door pharmacy located within a licensed dispensing medical practitioner's place of practice.

(25) "Distribute" means to deliver a drug or device other than by administering or dispensing.

(26) (a) "Drug" means:

(i) a substance recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(ii) a substance that is required by any applicable federal or state law or rule to be dispensed by prescription only or is restricted to administration by practitioners only;

(iii) a substance other than food intended to affect the structure or any function of the body of humans or other animals; and

(iv) substances intended for use as a component of any substance specified in Subsections (26)(a)(i), (ii), (iii), and (iv).

(b) "Drug" does not include dietary supplements.

(27) "Drug regimen review" includes the following activities:

(a) evaluation of the prescription drug order and patient record for:

(i) known allergies;

(ii) rational therapy-contraindications;

(iii) reasonable dose and route of administration; and

(iv) reasonable directions for use;

(b) evaluation of the prescription drug order and patient record for duplication of therapy;

(c) evaluation of the prescription drug order and patient record for the following interactions:

(i) drug-drug;

(ii) drug-food;

(iii) drug-disease; and

(iv) adverse drug reactions; and

(d) evaluation of the prescription drug order and patient record for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(28) "Drug sample" means a prescription drug packaged in small quantities consistent with limited dosage therapy of the particular drug, which is marked "sample", is not intended to be sold, and is intended to be provided to practitioners for the immediate needs of patients for trial purposes or to provide the drug to the patient until a prescription can be filled by the patient.

(29) "Electronic signature" means a trusted, verifiable, and secure electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(30) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to inpatients of a general acute hospital or specialty hospital licensed by the Department of Health under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

(32) "Legend drug" has the same meaning as prescription drug.

(33) "Licensed pharmacy technician" means an individual licensed with the division,

that may, under the supervision of a pharmacist, perform the activities involved in the technician practice of pharmacy.

(34) "Manufacturer" means a person or business physically located in Utah licensed to be engaged in the manufacturing of drugs or devices.

(35) (a) "Manufacturing" means:

(i) the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container; and

(ii) the promotion and marketing of such drugs or devices.

(b) "Manufacturing" includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

(c) "Manufacturing" does not include the preparation or compounding of a drug by a pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation, compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical analysis.

(36) "Medical order" means a lawful order of a practitioner which may include a prescription drug order.

(37) "Medication profile" or "profile" means a record system maintained as to drugs or devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to analyze the profile to provide pharmaceutical care.

(38) "Misbranded drug or device" means a drug or device considered misbranded under 21 U.S.C. Sec. 352 (2003).

(39) (a) "Nonprescription drug" means a drug which:

(i) may be sold without a prescription; and

(ii) is labeled for use by the consumer in accordance with federal law.

(b) "Nonprescription drug" includes homeopathic remedies.

(40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a person in Utah.

(41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.

(42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located outside the state that is licensed and in good standing in another state, that:

(a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in this state pursuant to a lawfully issued prescription;

(b) provides information to a patient in this state on drugs or devices which may include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses; or

(c) counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs.

(43) "Patient counseling" means the written and oral communication by the pharmacist or pharmacy intern of information, to the patient or caregiver, in order to ensure proper use of drugs, devices, and dietary supplements.

(44) "Pharmaceutical administration facility" means a facility, agency, or institution in which:

(a) prescription drugs or devices are held, stored, or are otherwise under the control of the facility or agency for administration to patients of that facility or agency;

(b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist or pharmacy intern with whom the facility has established a prescription drug supervising relationship under which the pharmacist or pharmacy intern provides counseling to the facility or agency staff as required, and oversees drug control, accounting, and destruction; and

(c) prescription drugs are professionally administered in accordance with the order of a practitioner by an employee or agent of the facility or agency.

(45) (a) "Pharmaceutical care" means carrying out the following in collaboration with a prescribing practitioner, and in accordance with division rule:

(i) designing, implementing, and monitoring a therapeutic drug plan intended to achieve favorable outcomes related to a specific patient for the purpose of curing or preventing the patient's disease;

(ii) eliminating or reducing a patient's symptoms; or

(iii) arresting or slowing a disease process.

(b) "Pharmaceutical care" does not include prescribing of drugs without consent of a prescribing practitioner.

(46) "Pharmaceutical facility" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into this state.

(47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility engaged in the business of wholesale vending or selling of a prescription drug or device to other than a consumer or user of the prescription drug or device that the pharmaceutical facility has not produced, manufactured, compounded, or dispensed.

(b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical facility carrying out the following business activities:

(i) intracompany sales;

(ii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, if the activity is carried out between one or more of the following entities under common ownership or common administrative control, as defined by division rule:

(A) hospitals;

(B) pharmacies;

(C) chain pharmacy warehouses, as defined by division rule; or

(D) other health care entities, as defined by division rule;

(iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, for emergency medical reasons, including supplying another pharmaceutical facility with a limited quantity of a drug, if:

(A) the facility is unable to obtain the drug through a normal distribution channel in sufficient time to eliminate the risk of harm to a patient that would result from a delay in obtaining the drug; and

(B) the quantity of the drug does not exceed an amount reasonably required for immediate dispensing to eliminate the risk of harm;

(iv) the distribution of a prescription drug or device as a sample by representatives of a manufacturer; and

(v) the distribution of prescription drugs, if:

(A) the facility's total distribution-related sales of prescription drugs does not exceed 5% of the facility's total prescription drug sales; and

(B) the distribution otherwise complies with 21 C.F.R. Sec. 1307.11.

(48) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy.

(49) "Pharmacist-in-charge" means a pharmacist currently licensed in good standing who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally in full and actual charge of the pharmacy and all personnel.

(50) "Pharmacist preceptor" means a licensed pharmacist in good standing with one or more years of licensed experience. The preceptor serves as a teacher, example of professional conduct, and supervisor of interns in the professional practice of pharmacy.

(51) "Pharmacy" means any place where:

(a) drugs are dispensed;

(b) pharmaceutical care is provided;

(c) drugs are processed or handled for eventual use by a patient; or

(d) drugs are used for the purpose of analysis or research.

(52) "Pharmacy benefits manager or coordinator" means a person or entity that provides a pharmacy [~~benefit~~] benefits management [~~services~~] service as defined in Section 49-20-502 on behalf of a self-insured employer, insurance company, health maintenance organization, or other plan sponsor, as defined by rule.

(53) "Pharmacy intern" means an individual licensed by this state to engage in practice as a pharmacy intern.

(54) "Pharmacy technician training program" means an approved technician training program providing education for pharmacy technicians.

(55) (a) "Practice as a dispensing medical practitioner" means the practice of pharmacy, specifically relating to the dispensing of a prescription drug in accordance with Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, and division rule adopted after consultation with the Board of pharmacy and the governing boards of the practitioners described in Subsection (23)(a).

(b) "Practice as a dispensing medical practitioner" does not include:

(i) using a vending type of dispenser as defined by the division by administrative rule; or

(ii) except as permitted by Section 58-17b-805, dispensing of a controlled substance as defined in Section 58-37-2.

(56) (a) "Practice as a licensed pharmacy technician" means engaging in practice as a pharmacy technician under the general supervision of a licensed pharmacist and in accordance with a scope of practice defined by division rule made in collaboration with the board.

(b) "Practice as a licensed pharmacy technician" does not include:

(i) performing a drug utilization review, prescription drug order clarification from a prescriber, final review of the prescription, dispensing of the drug, or counseling a patient with respect to a prescription drug;

(ii) except as permitted by rules made by the division in consultation with the board, final review of a prescribed drug prepared for dispensing;

(iii) counseling regarding nonprescription drugs and dietary supplements unless delegated by the supervising pharmacist; or

(iv) receiving new prescription drug orders when communicating telephonically or electronically unless the original information is recorded so the pharmacist may review the prescription drug order as transmitted.

(57) "Practice of pharmacy" includes the following:

(a) providing pharmaceutical care;

(b) collaborative pharmacy practice in accordance with a collaborative pharmacy practice agreement;

(c) compounding, packaging, labeling, dispensing, administering, and the coincident distribution of prescription drugs or devices, provided that the administration of a prescription drug or device is:

(i) pursuant to a lawful order of a practitioner when one is required by law; and

(ii) in accordance with written guidelines or protocols:

(A) established by the licensed facility in which the prescription drug or device is to be administered on an inpatient basis; or

(B) approved by the division, in collaboration with the board and the Physicians Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be administered on an outpatient basis solely by a licensed pharmacist;

(d) participating in drug utilization review;

(e) ensuring proper and safe storage of drugs and devices;

(f) maintaining records of drugs and devices in accordance with state and federal law and the standards and ethics of the profession;

(g) providing information on drugs or devices, which may include advice relating to therapeutic values, potential hazards, and uses;

(h) providing drug product equivalents;

(i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy technicians;

(j) providing patient counseling, including adverse and therapeutic effects of drugs;

(k) providing emergency refills as defined by rule;

(l) telepharmacy; [~~and~~]

(m) formulary management intervention[~~.~~]; and

(n) prescribing and dispensing a self-administered hormonal contraceptive in accordance with Section 58-17b-626.

(58) "Practice of telepharmacy" means the practice of pharmacy through the use of telecommunications and information technologies.

(59) "Practice of telepharmacy across state lines" means the practice of pharmacy through the use of telecommunications and information technologies that occurs when the patient is physically located within one jurisdiction and the pharmacist is located in another jurisdiction.

(60) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

(61) "Prescribe" means to issue a prescription:

(a) orally or in writing; or

(b) by telephone, facsimile transmission, computer, or other electronic means of communication as defined by division rule.

(62) "Prescription" means an order issued:

(a) by a licensed practitioner in the course of that practitioner's professional practice or by collaborative pharmacy practice agreement; and

(b) for a controlled substance or other prescription drug or device for use by a patient

or an animal.

(63) "Prescription device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, and any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by or through a person or entity licensed under this chapter or exempt from licensure under this chapter.

(64) "Prescription drug" means a drug that is required by federal or state law or rule to be dispensed only by prescription or is restricted to administration only by practitioners.

(65) "Repackage":

(a) means changing the container, wrapper, or labeling to further the distribution of a prescription drug; and

(b) does not include:

(i) Subsection (65)(a) when completed by the pharmacist responsible for dispensing the product to a patient; or

(ii) changing or altering a label as necessary for a dispensing practitioner under Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, for dispensing a product to a patient.

(66) "Research using pharmaceuticals" means research:

(a) conducted in a research facility, as defined by division rule, that is associated with a university or college in the state accredited by the Northwest Commission on Colleges and Universities;

(b) requiring the use of a controlled substance, prescription drug, or prescription device;

(c) that uses the controlled substance, prescription drug, or prescription device in accordance with standard research protocols and techniques, including, if required, those approved by an institutional review committee; and

(d) that includes any documentation required for the conduct of the research and the handling of the controlled substance, prescription drug, or prescription device.

(67) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs and devices to the general public.

(68) (a) "Self-administered hormonal contraceptive" means a self-administered

hormonal contraceptive that is approved by the United States Food and Drug Administration to prevent pregnancy.

(b) "Self-administered hormonal contraceptive" includes an oral hormonal contraceptive, a hormonal vaginal ring, and a hormonal contraceptive patch.

(c) "Self-administered hormonal contraceptive" does not include any drug intended to induce an abortion, as that term is defined in Section 76-7-301.

[~~(68)~~] (69) "Self-audit" means an internal evaluation of a pharmacy to determine compliance with this chapter.

[~~(69)~~] (70) "Supervising pharmacist" means a pharmacist who is overseeing the operation of the pharmacy during a given day or shift.

[~~(70)~~] (71) "Supportive personnel" means unlicensed individuals who:

(a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed pharmacy technician in nonjudgmental duties not included in the definition of the practice of pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as those duties may be further defined by division rule adopted in collaboration with the board; and

(b) are supervised by a pharmacist in accordance with rules adopted by the division in collaboration with the board.

[~~(71)~~] (72) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-501.

[~~(72)~~] (73) "Unprofessional conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

[~~(73)~~] (74) "Veterinary pharmaceutical facility" means a pharmaceutical facility that dispenses drugs intended for use by animals or for sale to veterinarians for the administration for animals.

Section 2. Section **58-17b-501** is amended to read:

58-17b-501. Unlawful conduct.

"Unlawful conduct" includes:

(1) knowingly preventing or refusing to permit an authorized agent of the division to conduct an inspection pursuant to Section 58-17b-103;

(2) failing to deliver the license, permit, or certificate to the division upon demand, if it

has been revoked, suspended, or refused;

(3) (a) using the title "pharmacist," "druggist," "pharmacy intern," "pharmacy technician," or a term having similar meaning, except by a person licensed as a pharmacist, pharmacy intern, or pharmacy technician; or

(b) conducting or transacting business under a name that contains, as part of that name, the words "drugstore," "pharmacy," "drugs," "medicine store," "medicines," "drug shop," "apothecary," "prescriptions," or a term having a similar meaning, or in any manner advertising, otherwise describing, or referring to the place of the conducted business or profession, unless the place is a pharmacy issued a license by the division, except an establishment selling nonprescription drugs and supplies may display signs bearing the words "packaged drugs," "drug sundries," or "nonprescription drugs," and is not considered to be a pharmacy or drugstore by reason of the display;

(4) buying, selling, causing to be sold, or offering for sale, a drug or device that bears, or the package bears or originally did bear, the inscription "sample," "not for resale," "for investigational or experimental use only," or other similar words, except when a cost is incurred in the bona fide acquisition of an investigational or experimental drug;

(5) using to a person's own advantages or revealing to anyone other than the division, board, and its authorized representatives, or to the courts, when relevant to a judicial or administrative proceeding under this chapter, information acquired under authority of this chapter or concerning a method of process that is a trade secret;

(6) procuring or attempting to procure a drug or to have someone else procure or attempt to procure a drug:

(a) by fraud, deceit, misrepresentation, or subterfuge;

(b) by forgery or alteration of a prescription or a written order;

(c) by concealment of a material fact;

(d) by use of a false statement in a prescription, chart, order, or report; or

(e) by theft;

(7) filling, refilling, or advertising the filling or refilling of prescriptions for a consumer or patient residing in this state if the person is not licensed:

(a) under this chapter; or

(b) in the state from which he is dispensing;

(8) requiring an employed pharmacist, pharmacy intern, pharmacy technician, or authorized supportive personnel to engage in conduct in violation of this chapter;

(9) being in possession of a prescription drug for an unlawful purpose;

(10) dispensing a prescription drug to a person who does not have a prescription from a practitioner, except as permitted under Title 26, Chapter 55, Opiate Overdose Response Act, or Section 58-17b-626;

(11) dispensing a prescription drug to a person who the person dispensing the drug knows or should know is attempting to obtain drugs by fraud or misrepresentation;

[~~(11)~~] (12) selling, dispensing, distributing, or otherwise trafficking in prescription drugs when not licensed to do so or when not exempted from licensure; and

[~~(12)~~] (13) a person using a prescription drug or controlled substance that was not lawfully prescribed for the person by a practitioner.

Section 3. Section **58-17b-502** is amended to read:

58-17b-502. Unprofessional conduct.

"Unprofessional conduct" includes:

(1) willfully deceiving or attempting to deceive the division, the board, or their agents as to any relevant matter regarding compliance under this chapter;

(2) (a) except as provided in Subsection (2)(b):

(i) paying or offering rebates to practitioners or any other health care providers, or receiving or soliciting rebates from practitioners or any other health care provider; or

(ii) paying, offering, receiving, or soliciting compensation in the form of a commission, bonus, rebate, kickback, or split fee arrangement with practitioners or any other health care provider, for the purpose of obtaining referrals.

(b) Subsection (2)(a) does not apply to:

(i) giving or receiving price discounts based on purchase volume;

(ii) passing along pharmaceutical manufacturer's rebates; or

(iii) providing compensation for services to a veterinarian.

(3) misbranding or adulteration of any drug or device or the sale, distribution, or dispensing of any outdated, misbranded, or adulterated drug or device;

(4) engaging in the sale or purchase of drugs or devices that are samples or packages bearing the inscription "sample" or "not for resale" or similar words or phrases;

(5) except as provided in Section 58-17b-503 or Part 9, Charitable Prescription Drug Recycling Act, accepting back and redistributing any unused drug, or a part of it, after it has left the premises of any pharmacy, unless the drug is in a unit pack, as defined in Section 58-17b-503, or the manufacturer's sealed container, as defined in rule;

(6) an act in violation of this chapter committed by a person for any form of compensation if the act is incidental to the person's professional activities, including the activities of a pharmacist, pharmacy intern, or pharmacy technician;

(7) violating [~~Federal Title II, P.L. 91, Controlled Substances Act,~~]:

(a) the federal Controlled Substances Act, Title II, P.L. 91-513;

(b) Title 58, Chapter 37, Utah Controlled Substances Act[~~.~~]; or

(c) rules or regulations adopted under either act;

(8) requiring or permitting pharmacy interns or technicians to engage in activities outside the scope of practice for their respective license classifications, as defined in this chapter and division rules made in collaboration with the board, or beyond their scope of training and ability;

(9) administering:

(a) without appropriate training, as defined by rule;

(b) without a physician's order, when one is required by law; and

(c) in conflict with a practitioner's written guidelines or written protocol for administering;

(10) disclosing confidential patient information in violation of the provisions of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, as amended, or other applicable law;

(11) engaging in the practice of pharmacy without a licensed pharmacist designated as the pharmacist-in-charge;

(12) failing to report to the division any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court for conduct that in substance would be considered unprofessional conduct under this section; [~~and~~]

(13) as a pharmacist or pharmacy intern, compounding a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner[~~.~~]; and

(14) failing to act in accordance with Section 58-17b-626 when prescribing and dispensing a self-administered hormonal contraceptive.

Section 4. Section **58-17b-626** is enacted to read:

58-17b-626. Authority to prescribe and dispense certain contraceptives.

(1) (a) A pharmacist may prescribe and dispense a self-administered hormonal contraceptive if the pharmacist:

(i) has completed a course on the prescribing of contraceptives that has been approved by the board or the Accreditation Council for Pharmacy Education;

(ii) if more than two years has passed since the pharmacist has completed the course described in Subsection (1)(a)(i), has, within the last two years, completed a continuing education course on contraceptives that has been approved by the board;

(iii) submits a copy of the certificate of completion for the courses described in Subsections (1)(a)(i) and (ii) to the division;

(iv) notifies the division that the pharmacist intends to prescribe and dispense self-administered hormonal contraceptives under this section; and

(v) prescribes and dispenses self-administered hormonal contraceptives in accordance with this chapter.

(b) A pharmacist who currently prescribes and dispenses a self-administered hormonal contraceptive shall maintain the certificate of completion for courses taken to fulfill the requirements described in Subsections (1)(a)(i) and (ii) and make the certificates of completion available upon request.

(2) A pharmacist may not prescribe a self-administered hormonal contraceptive under this section to an individual who is under 18 years of age.

(3) For each new patient requesting a prescription for a self-administered hormonal contraceptive, and at least every 12 months for each returning patient requesting a self-administered hormonal contraceptive, a participating pharmacist shall:

(a) obtain a completed self-screening risk assessment questionnaire approved by the board;

(b) follow the procedure described in Subsection (4) to ensure that the patient does not have any contraindicating factors;

(c) prescribe a self-administered hormonal contraceptive, if clinically appropriate, or

refer the patient to a primary care or women's health care practitioner;

(d) provide the patient with the documentation required in Subsection (5);

(e) advise the patient to consult with a primary care or women's health care practitioner; and

(f) document the encounter and maintain records in accordance with Subsection (7).

(4) (a) Before prescribing contraceptive supplies to a patient, a pharmacist shall evaluate the patient's health and medical history to determine whether the patient:

(i) has any contraindicating conditions, including uncontrolled hypertension;

(ii) is pregnant;

(iii) is taking any contraindicating medications; or

(iv) is currently using any self-administered hormonal contraceptive.

(b) A pharmacist shall use a standard procedures algorithm approved by the board as part of the patient assessment described in Subsection (4)(a).

(c) If the results of the evaluation in Subsection (4)(a) indicate that it is unsafe to prescribe a self-administered hormonal contraceptive to a patient, the pharmacist:

(i) may not prescribe a self-administered hormonal contraceptive to the patient; and

(ii) shall refer the patient to a primary care or women's health care practitioner.

(5) The pharmacist shall provide the patient with:

(a) written information regarding:

(i) the importance of seeing the patient's primary care practitioner or women's health care practitioner to obtain recommended tests and screening; and

(ii) the effectiveness and availability of long-acting reversible contraceptives as an alternative to self-administered hormonal contraceptives; and

(b) a copy of the record of the encounter that includes:

(i) the patient's completed self-assessment tool; and

(ii) the contraceptives prescribed and dispensed, or the basis for not prescribing and dispensing a contraceptive.

(6) If a pharmacist prescribes a self-administered hormonal contraceptive to a patient, the pharmacist shall:

(a) at minimum, counsel the patient on:

(i) the appropriate administration and storage of the self-administered hormonal

contraceptive;

(ii) potential side effects and risks of the self-administered hormonal contraceptive;

(iii) the need for backup contraception;

(iv) when to seek emergency medical attention;

(v) the risk of contracting a sexually transmitted infection or disease, and ways to reduce the risk of contraction; and

(vi) ways to contact the pharmacy with any follow-up questions; and

(b) dispense the self-administered hormonal contraceptive to the patient as soon as practicable after the pharmacist issues the prescription.

(7) (a) The pharmacist shall maintain a record of an encounter described in this section, including the written self-screening risk assessment questionnaire, for a minimum of five years and in accordance with applicable state and federal law.

(b) A pharmacist may maintain the records described in Subsection (7)(a) in an electronic health record maintained on the patient by the pharmacist.

(8) A pharmacist who prescribes a self-administered hormonal contraceptive to a patient under this section may not continue to prescribe and dispense a self-administered hormonal contraceptive to the patient more than three years after the date of the initial prescription without evidence that the patient has consulted with a primary care or women's health care practitioner during the preceding three years.

(9) (a) The board shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, establishing:

(i) the self-screening risk assessment questionnaire described in Subsection (3)(a); and

(ii) a standard procedures algorithm, described in Subsection (4)(b), to evaluate the safety of prescribing a self-administered hormonal contraceptive to a patient.

(b) The board may make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to:

(i) approve courses required under Subsections (1)(a)(i) and (ii) for a pharmacist who prescribes self-administered hormonal contraceptives under this section; and

(ii) develop prescribing standards and practices consistent with the requirements of this section.

(c) When making rules under this Subsection (9), the board shall seek

recommendations from the Department of Health and the Physicians Licensing Board.

(10) Nothing in this section shall be read to require a pharmacist to provide the services described in this section.

Legislative Review Note
Office of Legislative Research and General Counsel